

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Subhashis Banerjee *et al.*

Serial No.: 10/622205

Filed: July 18, 2003

For: TREATMENT OF SKIN AND NAIL  
DISORDERS USING TNF $\alpha$  INHIBITORS

Attorney Docket No.: BPI-195

Group Art Unit: 1641

Examiner: Not Yet Assigned

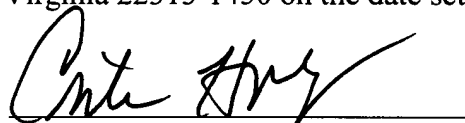
MS Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Certificate of First Class Mailing (37 CFR §1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Non-Fee Amendment  
Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on the date set forth below.

\_\_\_\_\_  
Date of Signature and of Mail Deposit

By:

  
Cristin E. Howley

INFORMATION DISCLOSURE STATEMENT

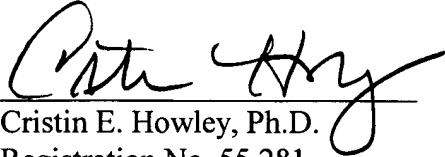
Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form SB-08, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

  
Cristin E. Howley, Ph.D.  
Registration No. 55,281  
Agent for Applicant

28 State Street  
Boston, MA 02109  
(617) 227-7400

Date: April 15, 2004

GAD/EAH/CEH/alf  
Enclosures



PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	1	of	3	Attorney Docket Number	BPI-195
-------	---	----	---	------------------------	---------

**Complete if Known**

Application Number	10/622205
Filing Date	July 18, 2003
First Named Inventor	Subhashis Banerjee
Art Unit	1641
Examiner Name	Not Yet Assigned
Attorney Docket Number	BPI-195

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	6,090,382	07/18/2000	Salfeld <i>et al.</i>	
	A2	6,258,562 B1	07/10/2001	Salfeld <i>et al.</i>	
	A3	6,509,015 B1	01/21/2003	Salfeld <i>et al.</i>	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A4	Asadullah <i>et al.</i> "A high prevalence of cytomegalovirus antigenaemia in patients with moderate to severe chronic plaque psoriasis: an association with systemic tumour necrosis factor $\alpha$ overexpression." <i>Br. J. Dermatol.</i> 1999 Jul;141(1):94-102	
	A5	Chaudhari <i>et al.</i> "Efficacy and safety of infliximab monotherapy for plaque-type psoriasis: a randomised trial." <i>Lancet.</i> 2001 Jun 9;357(9271):1842-7	
	A6	Davison <i>et al.</i> "Etanercept for severe psoriasis and psoriatic arthritis: observations on combination therapy." <i>Br. J. Dermatol.</i> 2002 Oct;147(4):831-2	
	A7	Elewski "Infliximab for the treatment of severe pustular psoriasis." <i>J. Am. Acad. Dermatol.</i> 2002 Nov;47(5):796-7	
	A8	Iyer <i>et al.</i> "Etanercept for severe psoriasis and psoriatic arthritis: observations on combination therapy." <i>Br. J. Dermatol.</i> 2002 Jan;146(1):118-21	
	A9	Kamarashev <i>et al.</i> "Generalised pustular psoriasis induced by cyclosporin a withdrawal responding to the tumour necrosis factor alpha inhibitor etanercept." <i>Dermatology.</i> 2002;205(2):213-6	
	A10	Kirby <i>et al.</i> "Successful treatment of severe recalcitrant psoriasis with combination infliximab and methotrexate." <i>Clin. Exp. Dermatol.</i> 2001 Jan;26(1):27-9	
	A11	Mackiewicz <i>et al.</i> "Dual effects of caspase-1, interleukin-1 $\beta$ , tumour necrosis factor- $\alpha$ and nerve growth factor receptor in inflammatory myopathies." <i>Clin. Exp. Rheumatol.</i> 2003 Jan-Feb;21(1):41-8	
	A12	Mang <i>et al.</i> "Response of severe psoriasis to infliximab." <i>Dermatology.</i> 2002;204(2):156-7	
	A13	Mease <i>et al.</i> "Etanercept in the treatment of psoriatic arthritis and psoriasis: a randomised trial." <i>Lancet.</i> 2000 Jul 29;356(9227):385-90	
Examiner Signature		Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/622205
				Filing Date	July 18, 2003
				First Named Inventor	Subhashis Banerjee
				Art Unit	1641
				Examiner Name	Not Yet Assigned
Sheet	2	of	3	Attorney Docket Number	BPI-195

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	B1	Moretti <i>et al.</i> "Vitiligo and epidermal microenvironment: possible involvement of keratinocyte-derived cytokines." <i>Arch. Dermatol.</i> 2002 Feb;138(2):273-4		
	B2	Moretti <i>et al.</i> "New insights into the pathogenesis of vitiligo: imbalance of epidermal cytokines at sites of lesions." <i>Pigment Cell Res.</i> 2002 Apr;15(2):87-92		
	B3	Murota H <i>et al.</i> "Disruption of tumor necrosis factor receptor p55 impairs collagen turnover in experimentally induced sclerodermic skin fibroblasts." <i>Arthritis Rheum.</i> 2003 Apr;48(4):1117-25		
	B4	Newland <i>et al.</i> "Rapid response to infliximab in severe pustular psoriasis, von Zumbusch type." <i>Int. J. Dermatol.</i> 2002 Jul;41(7):449-52		
	B5	O'Quinn <i>et al.</i> "The effectiveness of tumor necrosis factor $\alpha$ antibody (infliximab) in treating recalcitrant psoriasis: A report of 2 cases." <i>Arch. Dermatol.</i> 2002 May;138(5):644-8		
	B6	Reuss-Borst <i>et al.</i> "Sweet's syndrome associated with myelodysplasia: possible role of cytokines in the pathogenesis of the disease." <i>Br. J. Haematol.</i> 1993 Jun;84(2):356-8		
	B7	Russell-Jones <i>et al.</i> "High-dose interferon and the U.K. guidelines for cutaneous melanoma." <i>Br. J. Dermatol.</i> 2002 Oct;147(4):832-4		
	B8	Schopf <i>et al.</i> "Treatment of psoriasis with the chimeric monoclonal antibody against tumor necrosis factor $\alpha$ , infliximab." <i>J. Am. Acad. Dermatol.</i> 2002 Jun;46(6):886-91		
	B9	Takematsu <i>et al.</i> "Absence of tumor necrosis factor- $\alpha$ in suction blister fluids and stratum corneum from patients with psoriasis." <i>Arch. Dermatol. Res.</i> 1989;281(6):398-400		
	B10	Tutuncu Z <i>et al.</i> "Anti-TNF therapy for other inflammatory conditions." <i>Clin. Exp. Rheumatol.</i> 2002 Nov-Dec;20(6 Suppl 28):S146-51		
Examiner Signature		Date Considered		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE</b>		<b>Complete if Known</b>	
		Application Number	10/622205
		Filing Date	July 18, 2003

				First Named Inventor	Subhashis Banerjee
				Art Unit	1641
				Examiner Name	Not Yet Assigned
Sheet	3	of	3	Attorney Docket Number	BPI-195

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	C1	WO 02/100330 A2	12/19/2002	Abbott Laboratories		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
Examiner Signature		Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.